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10/031,988	05/06/2002	Masataka Nadaoka	2002-0074A	8710

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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,988	NADAOKA ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-12,17-22,25-31 and 36-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-12,17-22,25-31 and 36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed December 19, 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 25-31, and 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 10-12, 17-22, 29-31, 36-33, and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Charm et al (US 5,985,675).

Charm et al reference teaches an analytical test device (i.e. biosensor) comprising a test strip 28 having a plurality of sequential layers comprising a rectangular pad of dry, compressed, cellulosic material 32 (i.e. development layer; porous material), a capture zone 38 and control zone 40 each comprising specific binding biomolecules (i.e. reagent immobilization part), a mobile phase 34 (i.e. marker reagent holding part) having specific binding biomolecules conjugated to optical probes (i.e. marker reagent), and a housing 12 with a raised chamber at an end of the test strip 28 opposite of the capture zone 38 and control zone 40 (i.e. space forming part is located only at a part upstream of said reagent immobilization part in a permeating direction of the inspection target solution) that produces an enlarged, rectangular application cavity 18 (i.e. cavity part). See column 4, line 64 to column 8, line 13; and Figure 1.

With respect to the intended use language "wherein said cavity part is a space into which the inspection target solution flows by a capillary phenomenon" (lines 12-13 of claim 1; lines 11-12 of claim 2) and "wherein an amount of inspection target solution which flows into said cavity part is regulated by a volume of said cavity part" (lines 16-17 of claim 1; 17-18 of claim 2), the teachings of Charm et al are fully capable of performing the claimed intended uses. Since the test strip 28 is made of cellulosic material, any solution that touches the test strip would necessarily flow through the test strip in a wicking manner, which is considered to read on the claimed "capillary

phenomenon." In addition, since the application cavity 18 consists of a limited space, solution that enters the cavity would necessarily be limited by that space, thereby reading on the claimed regulation by the cavity part.

With respect to claims 3 and 22, Charm et al teach that the absorbing-layer material in the application cavity part can expand and drive capillary flow laterally toward the end of the elongated housing (i.e. temporarily holds the inspection solution). See column 2, lines 36-43.

With respect to claims 10-11 and 29-30, Charm et al teach that the application cavity part has an open end 16 (i.e. means for externally checking whether the inspection target solution flowed inwards or not; space forming part is partially or entirely light permeable). See column 5, line 6 and Figure 1.

With respect to claims 12 and 31, Charm et al teach that one region of the mobile-phase support pad 33 is made of material that acts as a secondary filter capable of removing cells and is treated with sodium citrate (i.e. cell component destruction reagent part). See column 7, lines 10-17.

With respect to claims 17 and 36, Charm et al teach expansion aperture 19 (i.e. air vent). See column 5, line 7-9.

With respect to claims 19 and 38, Charm et al teach that the mobile-phase materials dissolve into biological fluid applied to the test device (i.e. reagent in a dry state). See column 8, lines 26-29.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al (US 5,985,675) in view of Bernstein et al (US 5,824,268).

Charm et al reference has been disclosed above, but fails to teach that the mobile-reagent pad is a cell component destruction reagent part.

Bernstein et al reference teaches a membrane treated with a buffer containing 0.1 M ammonium chloride to lyse red blood cells, in order to deliver sample to the test strip that is essentially plasma with little contamination from whole red blood cells. See column 10, lines 49-54.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Charm et al with a membrane treated with a buffer containing 0.1 M ammonium chloride to lyse red blood cells, as taught by Bernstein et al, in order to deliver sample to the test strip that is essentially plasma with little contamination from whole red blood cells. The membrane of Bernstein et al has the advantage of purifying a test sample for use in the device of Charm et al, thereby providing motivation for including the membrane in the device of Charm et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a membrane containing ammonium chloride to lyse red blood cells, as taught by Bernstein et al, in the device of Charm et al, since Charm et al teach means for preventing cells from interfering with assay results on the test strip, and a membrane that lyses red blood cells is one type of embodiment that prevents passage of red blood cells.

10. Claims 7 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al (US 5,985,675) in view of Killeen et al (US 5,166,051).

Charm et al reference has been disclosed above, but fails to teach that the mobile-reagent pad is a cell component shrinkage reagent part.

Killeen et al reference teaches a crenating agent in a membrane that functions to shrink RBC, in order to rigidify cells to make them less flexible so that they become trapped at the surface of a detection membrane and allow only the liquid analyte composition to flow through the membrane and penetrate the detection zone to provide to a viable signal. See column 5, lines 36-47.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Charm et al with a crenating agent in a membrane that functions to shrink RBC, as taught by Killeen et al, in order to rigidify cells to make them less flexible so that they become trapped at the surface of a detection membrane and allow only the liquid analyte composition to flow through the membrane and penetrate the detection zone to provide to a viable signal. The crenating agent of Bernstein et al has the advantage of purifying a test sample for use in the device of Charm et al, thereby providing motivation for including the agent in the device of Charm et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a membrane containing a crenating agent to shrink cells, as taught by Killeen et al, in the device of Charm et al, since Charm et al teach means for preventing cells from interfering with assay results on the

test strip, and a membrane that crenates cells is one type of embodiment that prevents passage of cells.

11. Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al (US 5,985,675) in view of Barr (US 4,252,538).

Charm et al reference has been disclosed above, but fails to teach that the mobile-reagent pad is a bleaching reagent part.

Barr reference teaches distilled water that bleaches red blood cells, in order to cause rupture of the membrane and produce transparent red blood cells. See column 10, lines 14-35.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Charm et al with distilled water that bleaches red blood cells, as taught by Barr, in order to cause rupture of the membrane and produce transparent red blood cells. The distilled water of Barr has the advantage of supplying clear red blood cells without optical contaminants in the device of Charm et al, thereby providing motivation of including distilled water in the device of Charm et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including distilled water, as taught by Barr, in the mobile-reagent pad of Charm et al, since Charm et al teach a test strip that prevents interference due to cells, and the distilled water of Barr causes the lysis of red blood cell, which is one means to produce cells that would not interfere with the optical readings of the assay.

12. Claims 9 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al (US 5,985,675) in view of Allen et al (US 5,416,000).

Charm et al reference has been disclosed above, but fails to teach that the cavity part has a volume of 20 μl or less.

Allen et al reference teaches a sample receiving element that receives about 10 μl volume of blood, in order to receive one or a series of small drops of blood. See column 5, lines 19-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify he apparatus of Charm et al with a sample receiving element that receives about 10 μl volume of blood, as taught by Allen et al, in order to receive one or a series of small drops of blood. The cavity volume taught by Allen et al has the advantage of requiring just one or two drops of blood in the device of Charm et al, thereby providing motivation for combining the cavity volume with the device of Charm et al. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a sample receiving element that receives about 10 μl volume of blood, as taught by Allen et al, in the device of Charm et al, since the test strip of Charm et al is capable of measuring liquid samples, and blood drops of Allen et al are one type of liquid sample. Furthermore, the sample receiving element of Allen et al is also placed in a test strip. See column 7, line 41.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-3, 6-12, 17-22, 25-31, and 36-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/069,845 in view of Charm et al (US 5,985,675).

The claims of the instant application recite a biosensor comprising a development layer for developing an inspection target solution as a specimen by making the inspection target solution permeate inwards, wherein said development layer includes a reagent immobilization part immobilized therein and a marker reagent holding part where a marker reagent which can be eluted by the development of the

inspection target solution is held, wherein said biosensor measures a bonding amount of the marker reagent in said reagent immobilization part, thereby qualitatively or quantitatively measuring components to be measured in the inspection target solution, and wherein said biosensor further comprises a space forming part which forms a cavity part, wherein said cavity part is a space into which the inspection target solution flows by a capillary phenomenon, and a marker reagent holding part for holding a marker reagent which can be eluted by flowing-in of the inspection target solution, in said cavity part, wherein said space forming part is located only at a part upstream of said reagent immobilization part in a permeating direction of the inspection target solution, and wherein an amount of inspection target solution which flows into said cavity part is regulated by a volume of said cavity part.

Claims 1-25 of the copending application discloses a biosensor comprising a development layer wherein an inspection target solution is developed, and further comprising at least a marker reagent part where a marker reagent is held so as to be dissolved by the development of the inspection target solution in a part of the development layer, as well as a reagent immobilization part where a reagent which specifically reacts to an analysis target in the inspection target solution is immobilized in a part of the development layer. Claims 1-25 of the copending application also disclose directional permeation of the inspection target solution. With regards to the limitation "measures a bonding amount of the marker reagent in said reagent immobilization part, thereby qualitatively or quantitatively measuring components to be measured in the inspection target solution" in the instant application, since the copending application is a

biosensor that develops an inspection target solution and also comprises a marker reagent part and reagent immobilization part, the device of the copending application would necessarily have the capability of measuring "a bonding amount" between the marker reagent and the reagent immobilization part, which would inherently include either "qualitatively or quantitatively" measuring components in the inspection target solution.

However, claims 1-25 of the copending application fails to teach a space forming part which forms a cavity part and wherein the space forming part is located only at a part upstream of said reagent immobilization part in a permeating direction of the inspection target solution.

Charm et al reference teaches a housing 12 with a raised chamber at an end of a test strip 28 opposite of capture zone 38 and control zone 40, wherein the raised chamber produces an enlarged, rectangular application cavity 18, in order to provide a metered liquid sample onto the test strip and to provide a space in which an absorbing-layer material within the cavity can expand and contact the surrounding walls of the cavity, thereby providing a capillary force to drive liquid sample onto the test strip. See column 2, lines 25-58; column 4, line 64 to column 8, line 13; and Figure 1.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus in claims 1-25 of the copending application with a housing 12 with a raised chamber at an end of a test strip 28 opposite of capture zone 38 and control zone 40, wherein the raised chamber produces an enlarged, rectangular application cavity 18, as taught by Charm et al, in order to provide a metered liquid

sample onto the test strip and to provide a space in which an absorbing-layer material within the cavity can expand and contact the surrounding walls of the cavity, thereby providing a capillary force to drive liquid sample onto the test strip. The advantages of metering liquid sample and providing an initial capillary force expedites the assay process without using up too much sample, thereby providing the motivation to combine the rectangular application cavity 18 of Charm et al with the apparatus of claims 1-25 of the copending application. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the rectangular application cavity 18 of Charm et al with claims 1-25 of the copending application, since claims 1-25 of the copending application teach a biosensor with parts that interact with an inspection target solution in series, and the introduction of sample through a rectangular application cavity, as taught by Charm et al, is one type of means to introduce a target solution into a biosensor at one location for interaction with different biosensor parts in series.

This is a provisional obviousness-type double patenting rejection.

15. The above provisional obviousness-type double patenting rejection is representative of double patenting rejections that are necessary between the instant application and a number of copending applications. The following list discloses the serial numbers of the other copending applications which would require similar provisional obviousness-type double patenting rejections as applied supra: 10,133,698

(claims 1 and 3-17); 10,398,711 (claims 1-19); 10,048,727 (claims 1-11); 10,242,672 (claims 14-17).

Response to Arguments

16. The Examiner thanks Applicants for providing copies of the foreign priority documents, as received on December 19, 2005.

17. Applicant's arguments with respect to claims 1-3, 6-12, 17-22, 25-31, and 36-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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02/24/06